

### **REMARKS**

The Examiner has imposed both restriction and election requirements upon the Applicant's Attorney ("Applicant"). Applicant's comments are below.

### **APPLICANTS' ELECTION**

The Examiner has imposed a restriction requirement and requested that Applicants elect one of three identified groups of claims for prosecution in connection with the present application. The groups of claims are as follows:

- |            |   |
|------------|---|
| Group I:   | Claims 1-23 and 28, drawn to compositions comprising a polymer formulation and an interferon for the delivery of interferon.                        |
| Group II:  | Claims 24-26, drawn to a composition comprising a polymer formulation, an interferon for the delivery of interferon and an additional active agent. |
| Group III: | Claims 27 and 30-34, drawn to a process of preparation of the compositions.   |

Applicants respectfully elect Group I, claims 1-23 and 28, **with traverse**.

### **APPLICANTS' TRAVERSAL OF ELECTION REQUIREMENT**

With respect to Applicants' traversal, Applicants respectfully state:

Regarding the Restriction Requirement, the Office Action asserts that "The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: at the time of filing the use of lipid formulations for the delivery of interferon as set forth in claim 1. See the PCT search report citing and explaining the teachings of X ref FR 2 786 98 A [sic]." (Office Action at page 3).

Applicants respectfully submit that the reasons given by the Office Action for the species allegedly lacking the same or corresponding special technical features are improper. Applicants

respectfully direct the Examiner's attention to Rule 13.2 of the Regulations Under the Patent Cooperation Treaty ("PCT Rules"), which states

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. **The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.**

(Rule 13.2. *See also* MPEP § 1850, page 1800-96. (emphasis added)). Applicants also respectfully direct the Examiner's attention to page 1800-99 of the MPEP, which states

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims.

\* \* \*

If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

(MPEP § 1850, page 1800-99).

Applicants respectfully submit that the independent claims of the application are patentable over the prior art.

A finding of Anticipation by a reference requires that the reference teach all limitations of the anticipated claims. USPN 6,630,171 (corresponds to FR 2 786 098). USPN 6,630,171 fails to meet this requirement at least because it fails to teach formulations that include a surfactant, which is a feature that is shared by all claims. Accordingly, all of the claims do share a special technical feature and thus do possess unity of invention.

Applicants respectfully request withdrawal of the restriction and election of species requirements, and respectfully request consideration on the merits and allowance of all claims.

Applicants reserve the right to file a divisional application for the non-elected claims during the pendency of this application.

### **ELECTION OF SPECIES**

The Examiner has also requested an election of species. Applicants select the polyglutamate and interferon alpha.

### **CONCLUSION**

Applicants respectfully request that this application be examined on the merits at the earliest possible time. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the telephone number of the undersigned below.

Applicant believes no fee is due with this response. If a fee is due, however, please charge our Deposit Account No. 50-2228, under Order No. 022290.0160PTUS from which the undersigned is authorized to draw.

Dated: November 2, 2009

Respectfully submitted,

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